

## REMARKS

Claims 1-18 and 29-41 are currently pending. All claims stand rejected. Claims 1-18, 32-38, and 40-41 have been canceled. Claim 42 is hereby added. The amendments are fully supported by the specification generally, and specifically in Fig. 16. No new matter has been added.

The specification has been amended both to correct the length of the abstract and to identify the sequence listing identifiers. The outstanding objections are now moot.

The claim objections are now moot in light of the instant amendments.

### 35 USC §112, second paragraph

The outstanding rejection under section 112, second paragraph is now moot in view of the instant amendments.

### 35 USC §112, first paragraph

Claims 1-5, 7, 8 and 39-41 stand rejected under section 112, first paragraph, for failing to comply with the written description requirement. Applications traverse.

The rejection is now moot in view of the instant amendments. With respect to claim 39, Applicants submit that the claim requires the elements of c5-12 (SEQ ID NO.5) and at least one “cis-acting regulatory element comprising SRE (SEQ ID NO.1); MEF-1 (SEQ ID NO.2); MEF-2 (SEQ ID NO.3); or TEF-1 (SEQ ID NO.4).” Such a claimed invention is supported by the instant specification, in particular Fig. 16. In that figure both SEQ ID NO.5 is depicted and the cis-acting regulatory elements are shown within SEQ ID NO.5. This disclosure supports the claimed invention.

Accordingly, the rejection under section 112, first paragraph should be withdrawn.

### 35 USC §102

Claims 1-4 and 7 stand rejected under section 102(b) as being anticipated by Schwartz et al (US 5,298,422). Applicants traverse.

Firstly, the Patent Office has failed to meet its burden to show that all elements of the claimed invention have been anticipated by the cited reference, Schwartz et al. Instead, the Patent Office misapplies case law to suggest that the burden is upon the Applicant to prove novelty. The citation of *In re Best* to suggest that the burden is upon the Applicant is incorrect. Actually, *In re Best* addresses an inherent teaching in the prior art and only shifts the burden of proof to the applicant when “ the Patent Office has **reason to believe that a functional limitation** asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on” See Page 1254-1255 (citing *In re Swinehart*, 58 CCPA 1027, 1031, 439 F.2d 210, 212-13, 169 USPQ 226, 229) (emphasis added). In this instance, the Patent Office is attempting to inappropriately use case law related to an inherent anticipation to support an anticipation rejection not based on inherency.

Notwithstanding the improper use of *In re Best*, Applicants submit that Schwartz et al fails to disclose each and every element of the claimed invention. In particular, Schwartz et al. fails to disclose a sequence similar to that of SEQ ID NO.5 – not even a sequence of 300 nucleotides or greater.

Accordingly, the rejection under §102 should be withdrawn.

### 35 USC §103

Claims 1-5, 7 and 8 stand rejected under section 103(a) as being unpatentable over Draghia-Akli et al. (US 7,241,744). Applicants traverse.

Errantly, the Patent Office has purported that SEQ ID NO.1 in Draghia-Akli to be a promoter; however, SEQ ID NO.1 is a protein sequence that is identified as a GHRH analog.

For the sake of progressing prosecution, Applicants submit that the Patent Office might have had in mind SEQ ID NO.7 in Draghia-Akli, which is a nucleotide sequence identified as a eukaryotic promoter c5-12. This sequence fails to render obvious the claimed invention related to instant SEQ ID NO.5. The sequence lengths are substantially different (323 nucleotides in Draghia-Akli and 335 in instant application). Furthermore, the alignment between the two sequences results in 96.1% similarity. Attachment 1 is provided to show the alignment performed at <http://www.ebi.ac.uk/Tools/emboss/align/>.

Accordingly, the differences are such that the teachings of Draghia-Akli would not have rendered the instant invention related to SEQ ID NO.5 obvious. The rejection should be withdrawn.

In conclusion, Applicants submit that the pending claims are in condition for allowance. Applicants respectfully request an early indication of same. The Patent Office is invited to contact the undersigned representative should that help to move the instant case to allowance.

Respectfully Submitted,

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Gap extension penalty	0.5
Needle output	needle-20090401-0310494607.output
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#####

# Program: needle

# Rndate: Wed Apr 01 03:10:50 2009

# Align\_format: srspair

# Report\_file: /ebi/extserv/old-work/needle-20090401-0310494607.output

#####

# =====

#

# Aligned\_sequences: 2

# 1: SEQ

# 2: SEQ

# Matrix: EBLOSUM62

# Gap\_penalty: 10.0

# Extend\_penalty: 0.5

#

# Length: 335

# Identity: 322/335 (96.1%)

# Similarity: 322/335 (96.1%)

# Gaps: 12/335 ( 3.6%)

# Score: 2030.0

#

#

# =====

```
SEQ      1  cggccgtccgccttcggcaccatcctcacgacacccaaatatggcgacgg      50
          |||
SEQ      1  cggccgtccgccttcggcaccatcctcacgacacccaaatatggcgacgg      50

SEQ     51  gtgaggaatggtggggagttattttagagcggtaggaaggtgggcagg      100
          |||
SEQ     51  gtgaggaatggtggggagttattttagagcggtaggaaggtgggcagg      100

SEQ     101  cagcaggtgttggcgtctaaaaataactcccgaggattattttagagc      150
          |||
SEQ     101  cagcaggtgttggcgtctaaaaataactcccgaggattattttagagc      150

SEQ     151  ggaggaatggtggacacccaaatatggcgacggttcctcaccgcgcga      200
          |||
SEQ     151  ggaggaatggtggacacccaaatatggcgacggttcctcaccgcgcga      200

SEQ     201  tatttgggtgtccgccctcgccggggccgcattcctggggccgggcgg      250
          |||
SEQ     201  tatttgggtgtccgccctcgccggggccgcattcctggggccgggcgg      250

SEQ     251  tgctcccgcccgctcgataaaaggctccggggccggcgccgccacga      300
          |||
SEQ     251  tgctcccgcccgctcgataaaaggctccggggccggcgccgccacga      300

SEQ     301  gctacccggaggagcgggagcgccaagctctaga      335
          |||
SEQ     301  gctacccggaggagcgggagcgcg      323
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